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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/147,693 | 02/17/1999 | WERNER LUBITZ | P564-9005 | 2068 |

7590

11/26/2002

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| EXAMINER |
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SANDALS, WILLIAM O

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1636

DATE MAILED: 11/26/2002

26

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/147,693

Applicant(s)

Lubitz et al.

Examiner

William Sandals

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 28, 2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38-46, 48-65, and 69-76 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 38-45, 49-62, 69, and 70 is/are allowed.
- 6) ☒ Claim(s) 46, 48, 63-65, and 71-76 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. _____.
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Response to Amendment

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Response to Arguments

2. Amendments to the claims in Paper No. 25, filed October 28, 2002 have overcome the rejection of the claims under 35 USC 112, first paragraph in the previous office action, and the rejection is withdrawn.
3. Amendments to the claims in Paper No. 25 have overcome the rejection of the claims under 35 USC 112, second paragraph in the previous office action, and the rejection is withdrawn.
4. Amendments to the claims in Paper No. 25 have overcome the rejection of the claims under 35 USC 103 in the previous office action, and the rejection is withdrawn.
5. Amendments to the claims in Paper No. 25 have overcome the objection to the claims in the previous office action, and the objection is withdrawn.
6. New grounds for rejection are presented below.

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Claim Objections

7. Claim 48 is objected to because of the following informalities: Claim 48 depends from claim 47, and claim 47 has been canceled. Appropriate correction is required.
8. Claim 71 is objected to because of the following informalities: Claim 71 depends from claim 67, and claim 67 has been canceled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 46, 48, and 73-76 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 46 recites a genus of OR or OL operator sequences from lambdoid phages which have an increased thermostability compared to wild type sequence with regard to binding of a temperature sensitive repressor. The OR or OL operator is made by a method of mutation.

The OR and OL operator sequences from lambdoid phages are well known and described in the prior art literature as set forth in the instant specification at pages 1-3. The specification teaches that the prior art taught a mutant operator sequence which lost its' repressor activity, and

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that no other mutant operator sequences were taught in the prior art, and none were taught to have a temperature sensitive binding of the repressor protein. The sequence and structure of the genus of wild type operator sequences are well described in the prior art.

The specification and claims do not indicate what distinguishing structural attributes are shared by the genus of operators which have an increased thermostability compared to wild type operator sequences. The scope of the claims includes numerous structural variants of the genus of wild type operator sequences, and the genus is highly variant, since a significant number of structural differences is permitted. Although these types of changes are done routinely in the art, the specification and claims do not provide description as to what changes can or should be made. Structural features that could distinguish operators with increased thermostability from the wild type operators are missing from the disclosure. No common structural attributes identify members of the genus of operators with increased thermostability. General knowledge and the level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common structural attributes or characteristics that identify the genus of operators with increased thermostability, and because the genus of operators with increased thermostability are highly variant, the two examples described in the specification are insufficient to describe the genus of operators with increased thermostability. Thus, applicant was not in possession of the claimed genus.

Arguments set forth in Paper No. 25, page 9, assert that the claims meet the requirements for written description. The argument asserts that the process for making the mutant operator

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sequences is described, and that two sequences have been set forth in the specification which were made by the method, thereby providing adequate written description.

This argument is not found convincing because the specification does not point to structural features in the mutant operator by which one of skill in the art would identify such a mutant. The sequence and structure of the wild type operator sequences are well described in the prior art. The method of mutation taught in the instant specification described two exemplary sequences that have been mutated, each mutated at only a single base. No information is provided as to which if any other mutations at those particular locations would produce a mutant operator sequence, and no information is provided that would guide the skilled artisan to know if mutations at any other location in the sequence would produce a mutant operator sequence that has increased temperature sensitive binding of a temperature sensitive repressor protein. Therefore, the instant claims and specification fail to meet the requirements of written description.

11. Claims 63-65 and 71-72 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a vaccine. Vaccine making is a poorly enabled art which relies heavily on a trial and error process for discovery and development. The instant claims drawn to a

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vaccine do not provide the necessary information for the making of any vaccine. In order to do so, undue experimentation is required. Whether undue experimentation is needed is not based on a single factor, but rather a conclusion reached by weighing many factors. Many of these factors have been summarized in *In re Wands*, 858 F.2d 731, USPQ2d 1400 (Fed. Cir. 1988).

The Wands factors as they apply to the instant claimed invention are as follows:

- a- The quantity of experimentation necessary to reduce the instant claimed invention to practice would involve a trial and error process for testing and evaluating any prospective preparation for its' activity as a vaccine.
- b- Only prophetic guidance is provided in the manufacture of a vaccine. No examples of a vaccine have been provided.
- c- The nature of the invention is complex. Vaccine making is a poorly understood art.
- d- The state of the art of vaccine making is one of uncertainties, as stated by Miller (Curr. Opinion in Infectious Dis. Vol. 10:183-187, 1997).
- e- Those of skill in the art of vaccine making are presented with many problems which do not have clear and certain answers, as discussed by Gregoriadis (abstract: Pharm Res. Vol. 15(5):661-670, 1998).
- f- The uncertainty of making a vaccine is highlighted by Miller and by Gregoriadis, demonstrating the unpredictability of making a vaccine, and that one of skill in the art does not know how to predictably make a vaccine.

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g- The breadth of the claims encompass any vaccine which is made with a bacteria. In view of the foregoing reasons, there is no support in the claims or specification for the breadth of these claims.

g- Therefore, given the analysis above, it must be considered that the skilled artisan would have needed to have practiced considerable non-routine, trial and error experimentation to enable the full scope of the claims.

Allowable Subject Matter


12. Claims 38-45 and 49-62, 69 and 70 are allowed.

Conclusion

13. Certain papers related to this application are **welcomed** to be submitted to Art Unit 1636 by facsimile transmission. The FAX numbers are (703) 308-4242 and 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by the applicant or applicant's representative, and the FAX receipt from your FAX machine is proof of delivery. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications should be directed to Dr. William Sandals whose telephone number is (703) 305-1982. The examiner normally can be reached Monday through Thursday from 8:30 AM to 7:00 PM, EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the William Phillips, whose telephone number is (703) 305-3482.


TERRY MCKELVEY
PRIMARY EXAMINER

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William Sandals, Ph.D.
Examiner
November 21, 2002